



Congenital – under 2 years of age: 50,000 units/kg/body weight; ages 2 to 12 years: adjust dosage based on adult dosage schedule.

**Yaws, Bejel, and Pinta** – 1,200,000 units (1 injection).

**Prophylaxis** – for rheumatic fever and glomerulonephritis.

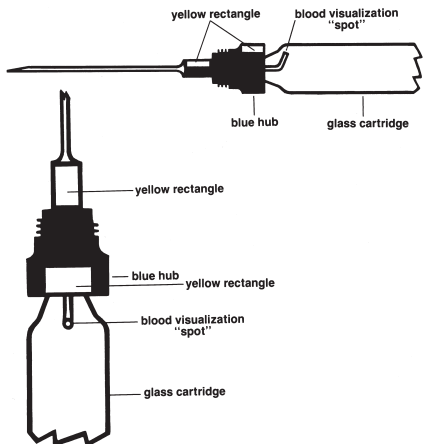
Following an acute attack, penicillin G benzathine (parenteral) may be given in doses of 1,200,000 units once a month or 600,000 units every 2 weeks.

#### Method of Administration

**Bicillin L-A is intended for intramuscular injection ONLY. Do not inject into or near an artery or nerve, or intravenously or admix with other intravenous solutions.** (See **WARNINGS** section).

Administer by DEEP INTRAMUSCULAR INJECTION in the upper, outer quadrant of the buttock. In neonates, infants and small children, the midlateral aspect of the thigh may be preferable. When doses are repeated, vary the injection site.

The **TUBEX®** cartridge for this product incorporates several features that are designed to facilitate the visualization of blood on aspiration if a blood vessel is inadvertently entered.



The design of this cartridge is such that blood which enters its needle will be quickly visualized as a red or dark-colored "spot." This "spot" will appear on the barrel of the glass cartridge immediately proximal to the blue hub. The **TUBEX** is designed with two orientation marks, in order to determine where this "spot" can be seen. First insert and secure the cartridge in the **TUBEX** injector in the usual fashion. Locate the yellow rectangle at the base of the blue hub. This yellow rectangle is aligned with the blood visualization "spot." An imaginary straight line, drawn from this yellow rectangle to the shoulder of the glass cartridge, will point to the area on the cartridge where the "spot" can be visualized. When the needle cover is removed, a second yellow rectangle will be visible. The second yellow rectangle is also aligned with the blood visualization "spot" to assist the operator in locating this "spot." If the 2 mL metal or plastic syringe is used, the glass cartridge should be rotated by turning the plunger of the syringe clockwise until the yellow rectangle is visualized. If the 1 mL metal syringe is used, it will not be possible to continue to rotate the glass cartridge clockwise once it is properly engaged and fully threaded; it can, however, then be rotated counterclockwise as far as necessary to properly orient the yellow rectangles and locate the observation area. (In this same area in some cartridges, a dark spot may sometimes be visualized prior to injection. This is the proximal end of the needle and does not represent a foreign body in, or other abnormality of, the suspension.)

Thus, before the needle is inserted into the selected muscle, it is important for the operator to orient the yellow rectangles so that any blood which may enter after needle insertion and during aspiration can be visualized in the area on the cartridge where it will appear and not be obscured by any obstructions.

After selection of the proper site and insertion of the needle into the selected muscle, aspirate by pulling back on the plunger. While maintaining negative pressure for 2 to 3 seconds, carefully observe the barrel of the cartridge in the area previously identified (see above) for the appearance of a red or dark-colored "spot."

Blood or "typical blood color" may *not* be seen if a blood vessel has been entered – only a mixture of blood and Bicillin L-A. The appearance of any discoloration is reason to withdraw the needle and discard the glass **TUBEX** cartridge. If it is elected to inject at another site, a new cartridge should be used. If no blood or discoloration appears, inject the contents of the cartridge slowly. Discontinue delivery of the dose if the subject complains of severe immediate pain at the injection site or if, especially in neonates, infants and young children, symptoms or signs occur suggesting onset of severe pain.

Some **TUBEX** cartridges may contain a small air bubble which should be disregarded, since it does not affect administration of the product. DO NOT clear any air bubbles from the cartridge or needle as this may interfere with the visualization of any blood or discoloration during aspiration.

Because of the high concentration of suspended material in this product, the needle may be blocked if the injection is not made at a slow, steady rate.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

#### HOW SUPPLIED

Bicillin® L-A (penicillin G benzathine suspension) is supplied in packages of 10 **TUBEX®** Sterile Cartridge-Needle Units as follows:

1 mL size, containing 600,000 units per **TUBEX®**, (21 gauge, thin-wall 1 inch needle for pediatric use), NDC 61570-146-10.

2 mL size, containing 1,200,000 units per **TUBEX®**, (21 gauge, thin-wall 1-1/4 inch needle), NDC 61570-147-10.

**Store in a refrigerator, 2° to 8°C (36° to 46°F).**

**Keep from freezing.**

#### Also Available

Bicillin L-A (penicillin G benzathine suspension) is also available in packages of 10 disposable syringes as follows:

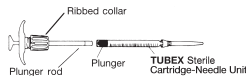
4 mL size, containing 2,400,000 units per syringe (18 gauge x 2 inch needle), NDC 61570-148-10.

**PLEASE NOTE: THE METAL TUBEX HYPODERMIC SYRINGE AND TUBEX FAST-TRAK SYRINGE HAVE BEEN DISCONTINUED AND REPLACED BY THE TUBEX INJECTOR. EXCHANGE OF THESE DISCONTINUED SYRINGES IS AVAILABLE, FREE OF CHARGE, FROM WYETH-AYERST DIRECTLY. FOR LOADING AND UNLOADING INFORMATION ON THESE DISCONTINUED SYRINGES, CONTACT THE MEDICAL AFFAIRS DEPARTMENT AT WYETH-AYERST LABORATORIES, P.O. BOX 8299, PHILADELPHIA, PA 19101.**

#### TUBEX® Injector

**NOTE: The TUBEX Injector is REUSABLE: do not discard.**

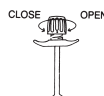
**DIRECTIONS FOR USE: BEFORE PROCEEDING, SEE IMPORTANT INFORMATION UNDER DOSAGE AND ADMINISTRATION SECTION.**



**NOTE: USE ASEPTIC TECHNIQUE FOR ALL MANIPULATIONS OF STERILE PARTS.**

**To load a TUBEX Sterile Cartridge-Needle Unit into the TUBEX Injector**

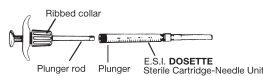
1. Turn the ribbed collar to the "OPEN" position until it stops.



2. Hold the Injector with the open end up and fully insert the **TUBEX** Sterile Cartridge-Needle Unit. Firmly tighten the ribbed collar in the direction of the "CLOSE" arrow.

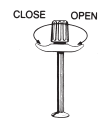
3. Thread the plunger rod into the plunger of the **TUBEX** Sterile Cartridge-Needle Unit until slight resistance is felt.

The Injector is now ready for use in the usual manner.



**To load an E.S.I. DOSETTE® Sterile Cartridge-Needle Unit into the TUBEX Injector**

1. Turn the ribbed collar to the "OPEN" position until it stops.



2. Hold the Injector with the open end up and fully insert the E.S.I. **DOSETTE** Sterile Cartridge-Needle Unit. Firmly tighten the ribbed collar in the direction of the "CLOSE" arrow.

3. Thread the plunger rod into the plunger of the E.S.I. **DOSETTE** Sterile Cartridge-Needle Unit until slight resistance is felt.

#### REFERENCES

1. SHAW, E.: Transverse myelitis from injection of penicillin. *Am. J. Dis. Child.*, 111:548, 1966.
2. KNOWLES, J.: Accidental intra-arterial injection of penicillin. *Am. J. Dis. Child.*, 111:552, 1966.
3. DARBY, C. et al: Ischemia following an intragluteal injection of benzathine-procaine penicillin G mixture in a one-year-old boy. *Clin. Pediatrics*, 12:485, 1973.
4. BROWN, L. & NELSON, A.: Postinfectious intravascular thrombosis with gangrene. *Arch. Surg.*, 94:652, 1967.
5. BORENSTINE, J.: Transverse myelitis and penicillin (Correspondence). *Am. J. Dis. Child.*, 112:166, 1966.
6. ATKINSON, J.: Transverse myelopathy secondary to penicillin injection. *J. Pediatrics*, 75:867, 1969.
7. TALBERT, J. et al: Gangrene of the foot following intramuscular injection in the lateral thigh: A case report with recommendations for prevention. *J. Pediatrics*, 70:110, 1967.
8. FISHER, T.: Medicolegal affairs. *Canad. Med. Assoc. J.*, 112:395, 1975.
9. SCHANZER, H. et al: Accidental intra-arterial injection of penicillin G. *JAMA*, 242:1289, 1979.

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Manufactured by: Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101

4. Engage the needle-cap assembly by pulling the cap down over the silver cartridge hub. The needle is fully engaged when the silver hub is completely covered.

The Injector is now ready for use in the usual manner.

#### To administer TUBEX/DOSETTE Sterile Cartridge-Needle Units

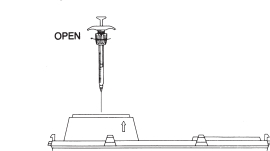
Method of administration is the same as with conventional syringe. Remove needle cover by grasping it securely; twist and pull. Introduce needle into patient, aspirate by pulling back slightly on the plunger, and inject.

#### To remove the empty TUBEX/DOSETTE Cartridge-Needle Unit and dispose into a vertical needle disposal container

1. Do not recap the needle. Disengage the plunger rod.

2. Hold the Injector, needle down, over a vertical needle disposal container and loosen the ribbed collar.

**TUBEX/DOSETTE** Cartridge-Needle Unit will drop into the container.



3. Discard the needle cover.

#### To remove the empty TUBEX/DOSETTE Cartridge-Needle Unit and dispose into a horizontal (mailbox) needle disposal container

1. Do not recap the needle. Disengage the plunger rod.

2. Open the horizontal (mailbox) needle disposal container. Insert **TUBEX/DOSETTE** Cartridge-Needle Unit, needle pointing down, halfway into container. Close the container lid on cartridge. Loosen ribbed collar; **TUBEX/DOSETTE** Cartridge-Needle Unit will drop into the container.

3. Discard the needle cover.

The **TUBEX** Injector is reusable and should not be discarded.

Used **TUBEX/DOSETTE** Cartridge-Needle Units should not be employed for successive injections or as multiple-dose containers. They are intended to be used only once and discarded.

**NOTE:** Any graduated markings on **TUBEX/DOSETTE** Sterile Cartridge-Needle Units are to be used only as a guide in administering doses.

**Wyeth-Ayerst does not recommend and will not accept responsibility for the use of any cartridge-needle units other than TUBEX or E.S.I. DOSETTE Cartridge-Needle Units in the TUBEX Injector.**

**TUBEX** is a registered trademark of Wyeth-Ayerst Laboratories.

